

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE)
WHOLESALE PRICE LITIGATION) MDL No. 1456
)

) Civil Action No. 01-CV-12257 PBS
)
)
) Judge Patti B. Saris
) Chief Magistrate Judge Marianne B. Bowler
)

THIS DOCUMENT RELATES TO
01-CV-12257-PBS AND 01-CV-339

BMS'S AND OTN'S RESPONSE TO PLAINTIFFS' LOCAL RULE 56.1 COUNTER-STATEMENT

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Dated: April 28, 2006

BMS'S AND OTN'S RESPONSE TO PLAINTIFFS' LOCAL RULE 56.1 COUNTER-STATEMENT

No.	STATEMENT	PLAINTIFFS' RESPONSE	EVIDENCE CITED IN SUPPORT OF DENIAL?	CONCLUSION
1	The Class 1 representative for BMS and OTN are David and Susan Ruth Aaronson ("Mrs. Aaronson"). (Consolidated Order Re: Motion For Class Certification, January 30, 2006.)	Admitted		Admitted
2	Mrs. Aaronson's husband, David Aaronson, was deposed on November 17, 2005. (Deposition of David Aaronson ("Aaronson Dep.")).	Admitted		Admitted
3	The Aaronsons have resided in Matthews, North Carolina since October 1992. (Aaronson Dep. Tr. 11.)	Admitted		Admitted
4	Mrs. Aaronson was diagnosed with ovarian cancer in May 2004. (<u>Id.</u> 15.)	Admitted		Admitted
5	Mrs. Aaronson began to receive chemotherapy treatment for ovarian cancer in July 2004. (<u>Id.</u> 35.)	Admitted		Admitted
6	The Class 2 representatives for BMS and OTN are Sheet Metal Workers National Health Fund ("Sheet Metal Workers") and Blue Cross Blue Shield of Massachusetts ("BCBS/MA"). (Consolidated Order Re: Motion For Class Certification, January 30, 2006.)	Admitted		Admitted
7	Sheet Metal Workers is a Taft-Hartley trust administered pursuant to the requirements of 29 U.S.C. § 186. (Third Amended Master Consolidated Class Action Complaint ("TAMCC") at ¶ 15.)	Admitted		Admitted
8	The Sheet Metal Workers fund is a multiemployer welfare fund subject to ERISA. (<u>Id.</u>)	Admitted		Admitted

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9	The Sheet Metal Workers' offices are located in Goodlettsville, Tennessee. (<u>Id.</u>)	Admitted		Admitted
10	Sheet Metal Workers has no offices, employees, property in Massachusetts, nor has it held meetings in Massachusetts. (Deposition of Glen Randle on behalf of Sheet Metal Workers National Health Fund, November 17, 2005, at 33-34.)	Admitted ¹		Admitted
11	BCBS/MA is the largest health insurance company in the state of Massachusetts and is located at 401 Park Drive, Boston, MA 02215. (http://www.bluecrossma.com/common/enUS/aboutUs , last visited on March 15, 2004.)	Admitted		Admitted
12	BCBS/MA provided insurance coverage to employers, including Taft-Hartley funds. (Deposition of Denise DeMaina, January 5, 2006 ("DeMaina Dep.") at 8-9.)	Admitted		Admitted
13	BMS is a Delaware corporation with its principal place of business located at 345 Park Avenue, New York, New York. (Third Amended Master Consolidated Class Action Complaint ¶ 94.)	Admitted		Admitted
14	OTN is a Delaware corporation with its principal place of business located at 395 Oyster Point Boulevard, South San Francisco, CA. (TAMCC ¶ 96.)	Admitted		Admitted
15	Seven BMS drugs are at issue on this motion: Blenoxane, Cytosan, Etopophos, Paraplatin, Rubex, Taxol and Vepesid ("BMS Subject Drugs"). Declaration of Raymond S. Hartman In Support of Plaintiffs' Claims of Liability and Calculation of Damages, Table 2 and App. G.2. ("Hartman Decl."). True and correct copies of Table 2 and App. G.2 are annexed as Exhibit A to the Declaration of Steven M. Edwards ("Edwards Decl.").	Admitted		Admitted

¹ Plaintiffs "counter-designate that Sheet Metal Workers made reimbursements based on AWP for drugs prescribed to beneficiaries in the State of Massachusetts."

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16	All of the BMS Subject Drugs are oncology drugs. (Meris Report and Declaration of Gregory K. Bell, Ph.D. in Support of BMS Motion For Summary Judgment ¶¶ 4, 12 ("Bell BMS Decl.")).	Admitted		Admitted
17	For the Subject Drugs, BMS established a list price, or WLP, at the time it launched the product. (Declaration of Zoltan Szabo in Support of Defendant Bristol-Myers Squibb Company's Memorandum in Opposition to Plaintiffs' Motion For Class Certification ¶ 2 ("Szabo Decl.")).	Admitted ²		Admitted
18	The WLP appears on invoices to wholesalers, and most of the sales to customers when a product is protected by a patent are within 5% of list price. (<i>Id.</i> , ¶¶ 2-3; Bell BMS Decl. ¶ 7(c), Exhs. D, E.)	Denied	None	Admitted
19	While a drug is protected by patent, BMS may periodically raise the WLP for a drug; but it does not do so unless it believes that it can obtain sales at the new price. (<i>Id.</i> ¶ 3.)	Denied, except admit that BMS may sometimes raise the WLP for a drug while it is protected by patent	None	Admitted
20	After a drug loses its patent protection, BMS generally does not make further changes to its list price. (<i>Id.</i> ¶ 3.)	Admitted as a general proposition but denied that no changes were ever made to the list price of a drug that lost its patent protection		Admitted

² Plaintiffs also "counter-designate that, at the time BMS established a WLP, it knew: (i) that an AWP would be established from that WLP based on a mark-up factor that BMS knew would be applied; (ii) what the AWP would be; (iii) that the AWP would be used by Medicare and other payors to reimburse providers; and (iv) that BMS would use the AWP for various purposes, including on price lists and other information provided to customers."

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21	From time to time, BMS offers discounts and rebates to downstream customers in order to meet competition. (<u>Id.</u> ¶ 4.)	Admitted to the extent that BMS offered discounts and rebates to downstream customers but denied in all other respects, particularly the statement that such discounts were merely offered "[f]rom time to time" when discounts and rebates – indeed massive ones – were offered nearly all of the time	None	Admitted
22	In the case of a discount, BMS will enter into a contract with a customer such as physician, hospital or HMO which entitles the customer to acquire the drug at a discounted price. (<u>Id.</u> ¶ 4.)	Admitted		Admitted
23	BMS will sell the drug to the wholesaler at the list price; the wholesaler will sell the drug to the customer at the discounted price; and then the wholesaler will receive a "chargeback" from BMS that makes it whole. (<u>Id.</u> n. 1.)	Admitted, except denied with respect to direct sales	None	Admitted
24	In the case of a rebate, the customer will receive money some time after the original sale based on the volume of purchases. (<u>Id.</u> ¶ 4, n. 1.)	Admitted		Admitted
25	Charles River Associates ("CRA"), an economic consulting firm, has performed an analysis to determine the extent to which the drugs at issue were sold within 5% of list price. (Bell BMS Decl. ¶ 6.)	Denied due to lack of knowledge (Plaintiffs have had no opportunity to examine Mr. Bell about his purported work). However, if true, Plaintiffs counter-designate that a substantial amount of sales near WLP would create marketplace expectations of small spreads	None. Also, plaintiffs declined the opportunity to question Dr. Bell, who has been made available by BMS. In any event, the cited analysis performed by CRA was based on the exact same raw data used by plaintiffs' own expert and the simple mathematics applied by CRA are obvious of the face of the BMS Bell Declaration.	Admitted

No.	STATEMENT	PLAINTIFFS' RESPONSE	EVIDENCE CITED IN SUPPORT OF DENIAL?	CONCLUSION
26	That analysis demonstrates that, during the period 1993 through 2002, 86.1% of BMS's net revenue for the Subject Drugs was achieved in transactions ("CRA"), an economic consulting firm, has performed an analysis to determine the extent to which the drugs at issue were sold within 5% of list price. (Bell BMS Decl. ¶ 6.)	Denied due to lack of knowledge (Plaintiffs have had no opportunity to examine Mr. Bell about his purported work)	None. Also, plaintiffs declined the opportunity to question Dr. Bell, who has been made available by BMS. In any event, the cited analysis performed by CRA was based on the exact same raw data used by plaintiffs' own expert and the simple mathematics applied by CRA are obvious of the face of the BMS Bell Declaration.	Admitted
27	Generally, while the products were protected by patents, more than 93% of net revenue was attributable to sales that were within 5% of WLP. (Id. ¶ 31(c), Exh. E.)	Denied due to lack of knowledge (Plaintiffs have had no opportunity to examine Mr. Bell about his purported work)	None. Also, plaintiffs declined the opportunity to question Dr. Bell, who has been made available by BMS. In any event, the cited analysis performed by CRA was based on the exact same raw data used by plaintiffs' own expert and the simple mathematics applied by CRA are obvious of the face of the BMS Bell Declaration.	Admitted

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28	When the products became subject to multi-source competition, that percentage went down to 29%, but within two minor exceptions (Rubex and Taxol in 2002) there continued to be significant sales of each product in each year within 5% of WLP. (<u>Id.</u> ¶ 31(c), Exh. E.)	Denied due to lack of knowledge (Plaintiffs have had no opportunity to examine Mr. Bell about his purported work)	None. Also, plaintiffs declined the opportunity to question Dr. Bell, who has been made available by BMS. In any event, the cited analysis performed by CRA was based on the exact same raw data used by plaintiffs' own expert and the simple mathematics applied by CRA are obvious of the face of the BMS Bell Declaration.	Admitted
29	BMS reports its list prices to industry publications such as Red Book, First Data Bank and MediSpan. (Affidavit of Denise M. Kaszuba, paragraph 1, sworn to on February 18, 2004 ("Kaszuba Aff").)	Admitted ³		Admitted
30	BMS has never communicated AWP's to the publications. (<u>Id.</u> ¶ 2; Szabo Dep. Tr. 133, 135-136, 151, annexed to the Edwards Decl. as Exh. B.)	Denied ⁴	None	Admitted
31	The publications calculate AWP's by multiplying the list price by a mark-up factor ranging from 20% to 25%. (Kaszuba Aff. ¶ 2; Deposition of Denise M. Kaszuba, August 18, 2005, at 97-101; Edwards Decl. ¶ 4, Exh. C.)	Admitted		Admitted

³ Plaintiffs also "counter-designate that, at the time BMS established a WLP, it knew: (i) that an AWP would be established from that WLP based on a mark-up factor that BMS knew would be applied; (ii) what the AWP would be; (iii) that the AWP would be used by Medicare and other payors to reimburse providers; and (iv) that BMS would use the AWP for various purposes, including on price lists and other information provided to customers."

⁴ Plaintiffs also "counter-designate that communicating WLP's to the publications is the formulaic equivalent of communicating AWP's, and that BMS directed the Red Book to use a 25% markup factor, and the Red Book did so."

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32	BMS does not control the mark-up factor that the publications use to calculate AWP's. (Deposition of Patricia Kay Morgan, January 11-12, 2005 ("Morgan Dep.") at 230; Edwards Decl. ¶ 4, Exh. E.)	Denied	None	Admitted
33	While once – in 1992 – BMS asked the publications to change their mark-up factor ranging from 20.5% to 25%, only Red Book acceded to that request; First Data Bank and MediSpan refused. (Kaszuba Aff. ¶ 3.)	Admitted		Admitted
34	In 2002, First Data Bank unilaterally changed the mark-up factor for all drugs to 25%, but the other publications did not follow suit. (<u>Id.</u> ¶ 4.)	Denied	None	Admitted
35	Various documents further confirm that BMS did not control AWP's. (Edwards Decl. ¶ 6, Exh. E.)	Denied	BMS Exhs. 1-14, 24-27, 58; Kaszuba Aff., ¶ 2; Szabo Exh. 1 ⁵	Denied, but no genuine disputed issue created. Referenced documents "speak for themselves" and do not support denial.
36	Beginning in 1999, BMS began to include language in its communications to publications notifying them that some customers receive manufacturer discounts or rebates that are not reflected in BMS's list prices. (Szabo Decl. ¶ 5.)	Denied	None	Admitted

⁵ "Plaintiffs also counter-designate that, at the time BMS established a WLP, it knew: (i) that an AWP would be established from that WLP based on a mark-up factor that BMS knew would be applied; (ii) what the AWP would be; (iii) that the AWP would be used by Medicare and other payors to reimburse providers; and (iv) that BMS would use the AWP for various purposes, including on price lists and other information provided to customers."

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37	An example shown to Kay Morgan of First Data Bank at her deposition states: "Wholesale and Direct List Prices, including those or the products listed herein, may not lower special offer prices. All products may be subject to negotiated discounts, rebates and chargebacks." (Morgan Dep. Ex. 41; Edwards Decl. ¶ 7, Exh. F.)	Admitted that the quote is an accurate reproduction of that statement as it appears in the document ⁶		Admitted
38	Ms. Morgan testified that, to her knowledge, this information had no impact on the way First Data Bank calculated AWP's. (Morgan Dep. Tr. 227; Edwards Decl. ¶ 5, Exh. D.)	Denied, as the question asked was objectionable and not cured	None	Admitted
39	Plaintiffs took the depositions of nine BMS sales representatives in the case. (Edwards Decl. ¶ 15, Exh. N.)	Admitted that Plaintiffs took the depositions of nine BMS sales representatives in the case. Admitted that those witnesses gave carefully crafted and rehearsed testimony that the therapeutic attributes of BMS drugs were discussed in meetings with customers and that customers asked those witnesses about reimbursement. Denied in all other respects. ⁷		Admitted
40	BMS sales representatives had no authority to provide discounts or negotiate prices. (Edwards Decl. ¶ 8, Exh. G.)	Admitted		Admitted
41	Medicare was aware of the spreads of certain BMS drugs, including Cytoxan, Rubex and Vepesid. (Edwards Decl. ¶¶ 13, 14, Exhs. L, M.)	Denied	None	Admitted

⁶ Plaintiffs also "counter-designate that, at the time BMS transmitted these prices to *First DataBank*, BMS knew: (i) that an AWP would be established from that WLP based on a mark-up factor that BMS knew would be applied; (ii) what the AWP would be; (iii) that the AWP would be used by Medicare and other payors to reimburse providers; and (iv) that BMS would use the AWP for various purposes, including on price lists and other information provided to customers."

⁷ Further, "Plaintiffs counter-designate that BMS emphasized to marketing and sales representatives the importance of reimbursement to OBOs (*see, e.g., BMS Exhs. 17, 49-50, 59-60*), and BMS marketing and sales representatives engaged in active campaigns to market the spread (*see, e.g., 17-18, 41, 48, 50-56*)."

No.	STATEMENT	PLAINTIFFS' RESPONSE	EVIDENCE CITED IN SUPPORT OF DENIAL?	CONCLUSION
42	CMS (Medicare) has claimed deliberative privilege for documents and information relevant to this case. (Edwards Decl. ¶ 15, Exh. N.)	Denied	None	Admitted
43	The OIG report on Physicians' Cost for Chemotherapy Drugs published in November 1992, depicts spreads for more than 400% for Cytosoxan and Rubex. (Edwards Decl. ¶ 14, Exh. M.)	Denied ⁸	Plaintiffs' Memorandum of Law in Opposition to the BMS Defendants' Motion for Summary Judgment at p. 26, citing April 6, 2006 Hartman Declaration ¶ 11(b) n.26.	BMS agrees with plaintiffs that he spread figure for the BMS drugs in the OIG Report should read "up to 143%" not "more than 400%." This 143% figure is consistent with the spreads calculated by Plaintiffs' own expert, Dr. Hartman, and thus show that the government was aware of the available spreads on BMS drugs
44	A letter from Ven-A-Care to Dr. Bruce Vladeck dated October 2, 1996, depicts spreads for Vepesid of more than 700%. (Edwards Decl. ¶ 13, Exh. L.)	Denied. Moreover, the letter is hearsay and is incomplete (no exhibits attached).	None	Admitted

⁸ Further, "Plaintiffs counter-designate that the report also states that: 'Our review was limited to a small judgemental sample of patients and physicians'; that only five physicians were surveyed (p. 4 and App. I); that '[t]he conclusions reached may not apply in all cases' (page 11); and that a recommendation was made to conduct a broader survey 'to assure widespread applicability' (page 11). It is also undisputed that HCFA disagreed with one of the recommendations because 'they lack assurance that a substantial number of physicians can obtain drugs at the lowest price available,' see pp. 12-13, and that HCFA generally believed that it required additional information. P. 3. It is also uncontested that the authors of this report discussed the spread between AWP and acquisition cost and that the report does not disclose the full extent of such spreads as reported by Dr. Hartman. See Berman Decl. Supporting Plaintiffs' Motion for Partial Summary Judgment, Ex. 1."

Dated: Boston, Massachusetts
April 28, 2006

Respectfully Submitted,

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